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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/891,943

06/26/2001

W. Michael Gallatin

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2656

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7590

03/21/2005

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/891,943	Applicant(s) GALLATIN ET AL.	
	Examiner Phillip Gambel	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12, 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 1/13/05, has been entered.
Claims 11, 12 and 14 have been amended.

Claims 11-14 are pending.

Claims 1-10 and 13 have been canceled.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's amendment, filed 1/13/05.
The rejections of record can be found in the previous Office Actions.

3. It is noted that applicant's amendment, filed 1/13/05, has updated the status of the priority documents, and maintains a claim for priority back to USSN 08/605,672, filed 2/22/96.

Applicant relies upon column 61, lines 64-67 of U.S. Patent No. 5,817,515, filed as USSN 08/605,672, to provide written support for the priority of the current claims.

While column 61, lines 64-67 of U.S. Patent No. 5,817,515 provides for treating bronchoalveolar lavage fluid with anti-alphaD antibodies with a presumption of blocking activation of resident alveolar macrophages by moderating the release of TNF-alpha,

however the claims are drawn broadly to methods of inhibiting TNF-alpha release from "any macrophage" with alphaD-specific "monoclonal" antibodies.

Applicant's reliance on generic disclosure of methods of treating with alpha-D-specific antibodies and possibly a single or limited species of treating bronchoalveolar lavage fluid with anti-alphaD antibodies with a presumption of blocking activation of resident alveolar macrophages by moderating the release of TNF-alpha does not provide sufficient direction and guidance to the "features" currently claimed.

It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

In addition, it is not clear from the record whether USSN 08/605,672 can provide adequate written support for the recitation of all of the elements of claims 11/ 12 (a), (b) and (c), currently amended in applicant's latest amendment, filed 1/13/05 including applicant's newly submitted amended as well as

For now, the priority date of the instant claims is deemed to be the filing date of parent application USSN 08/943,363, filed 10/3/97.

If applicant desires priority prior to 10/3/97; applicant is invited to point out and provide documentary support for the priority of the instant claims. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph

. If applicant desires priority prior to 1/1/91; applicant is invited to point out and provide documentary support for the priority of the instant claims. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

4. As pointed out previously and reiterated herein for applicant's convenience, applicant's amendment, filed 8/14/03, indicates that formal drawings have been submitted, however no such drawings appear for the scanned application.

Given the changes to Image File Wrapper at the USPTO, the examiner does not request another submission of drawings at this time. Such requirements that would be in compliance with 37 CFR 1.84 as set forth in the form PTO-948, mailed 2/11/03, will be considered and addressed if this application is placed in condition for allowance.

Again, the examiner apologizes for any inconvenience to applicant in this matter.

5. Upon reconsideration of applicant's amended claims, filed 1/13/5; the previous rejection under 35 U.S.C. 112, first paragraph, enablement has been withdrawn.

6. Claim 11, 12 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gallatin et al. (U.S. Patent No. 5,437,958) (see entire document) for the reasons of record.

Applicant's arguments, filed 1/13/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that an anticipatory reference must disclose each and every limitation of the claimed invention and that inherent characteristics must be necessarily be present in the thing described and that it would be so recognized by persons of ordinary skill.

Applicant submits that the prior art does not provide sufficient support for associating alphaD-specific antibodies with modulating TNFalpha activity and it would not have been so recognized by a worker of ordinary skill in the art reading the disclosure of Gallatin.

Applicant acknowledges that Gallatin describes methods of making alphaD-specific antibodies, the general use of β 2-specific antibodies without giving any particular examples of alphaD-specific antibodies.

Applicant submits that the mere fact that a certain thing may result from a given set of circumstances is not sufficient and there was no indication that anti-alphaD antibodies would act to modulate an intracellular event such as TNFalpha expression and release.

Applicant has acknowledged that Gallatin discloses the use of anti- α D antibodies for treating immune or inflammatory responses, but submitted that Gallatin does not give any particular examples nor suggest modulating TNF- α release

As pointed out previously and in contrast to applicant's assertions, Gallatin et al. teach methods of treating immune or inflammatory responses with antibodies that bind alphaD (see Background of the Invention, including column 3, paragraph 2; Brief Description of the Invention; Detailed Description of the Invention). Gallatin et al. provide further guidance that the nature of the inflammatory conditions associated with macrophages include atherosclerosis, multiple sclerosis and diabetes (column 5, paragraph 5), which are consistent with the instant disclosure (pages 14-15, overlapping paragraph and page 16, paragraph 1).

Again, the claimed functional limitations of inhibiting TNF α release from macrophages or phagocytes with alphaD-specific antibodies, including the α D I-domain specificity, would be inherent properties of the referenced methods to treat immune or inflammatory responses with inhibitory alphaD-specific antibodies.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Even though the claims are drawn to a mechanism by which the alphaD-specific antibodies inhibit immune or inflammatory responses, the claimed methods do not appear to distinguish the prior art teaching the same or nearly the same methods to achieve the same end result. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See MPEP 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to administer alphaD-specific antibodies inhibit immune or inflammatory responses.

Applicant's arguments are not found persuasive.

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7. Claims 11, 12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,432,404 for the reasons of record.

Applicant's arguments, filed 1/13/05, have been fully considered and have not been found convincing essentially for the reasons of record.

Applicant's amendment, filed 1/13/05, submit that upon notification of allowance of claims 11, 12 and 14 in the instant application, a terminal disclaimer with respect to claims 1-9 of U.S. Patent No. 6,432,404 will be filed.

8. Upon reconsideration of the Restriction Requirement in USSN 09/193,043 in conjunction with applicant's arguments filed 1/13/05,

the previous rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,251,395 has been withdrawn.

9 No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Phillip Gambel", followed by a long horizontal line.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
March 16, 2005